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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/639,614	08/11/2003	Katherine S. Tweden	7883.97-02	5399

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EXAMINER	
PELLEGRINO, BRIAN E	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/639,614	TWEDEN ET AL.	
	Examiner	Art Unit	
	Brian E Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a): In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-49,51-60 and 62-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-49,51-60 and 62-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/16/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 62-64,66,68 are rejected under 35 U.S.C. 102(a) as being anticipated by Sogard et al. (WO 98/12990). Fig. 3 shows a stent **10** having an outer surface with a covering **14** and Fig. 4 illustrates the inner surface can also have a covering **17**. In Fig. 6, Sogard shows both surfaces are covered. Sogard also discloses that an agent may be used with the stent, page 13, lines 9-13. Sogard additionally discloses the covering is ePTFE, page 12, lines 13-24. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure. Clearly, the device is capable of providing blood flow from a heart chamber to a coronary vessel.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 65,67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sogard et al. (WO 98/12990) in view of Tartaglia et al. (5637113). Sogard is explained supra. However, Sogard fails to disclose the agent is heparin. Tartaglia et al. teach the use of heparin with a covered stent, col. 6, lines 1-4. It would have been obvious to one

of ordinary skill in the art to use heparin with the polymer as taught by Tartaglia in the stent of Sogard such that it prevents restenosis and thrombosis.

Claims 41,43,47-49,51-53,55,58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5429144) in view of Knudson et al. (5755682). Wilk discloses a stent placed in a myocardial site in the compressed state and then expanding the stent, col. 1, lines 54-63. Wilk also discloses (col. 8, lines 48-55) the stent has an inner and outer covering of natural tissue, Figs. 8A,8B,9. Wilk additionally discloses the method is used for passage of blood from the left ventricle to the coronary artery, col. 5, lines 46-48,53-56. Wilk also discloses deploying the stent by catheter, i.e. percutaneous, col. 6, lines 24-34. However, Wilk fails to disclose an agent is used with the stent to limit thrombus formation. Knudson et al. teach that agents that reduce restenosis, col. 10, lines 5-9. Since the agent is to prevent restenosis, it can be construed that the agent limits thrombus formation. Restenosis is a re-narrowing or blockage of an artery caused by a build-up of substances, i.e. blood clotting, platelets, that may eventually block the flow of blood. It would have been obvious to one of ordinary skill in the art to use an agent as taught by Knudson with the stent of Wilk such that it prevents restenosis and thrombus formation.

Claims 41-49,51-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5429144) in view of Lee (5123917). Wilk is explained supra. However, Wilk fails to disclose an agent, such as heparin to be used with the stent to limit thrombus formation. Lee teaches that agents such as heparin are used with a PTFE graft-stent to limit thrombus formation, col. 4, lines 51-61. It would have been obvious to one of

ordinary skill in the art to use the heparin stent-graft of PTFE as taught by Lee in the method of Wilk such that it provides a graft that does not promote intimal tissue proliferation and limits thrombus formation.

Response to Arguments

Applicant's arguments filed 7/22/05 have been fully considered but they are not persuasive. In response to applicant's argument that Sogard fails to disclose a stent having "a configuration that resist deformation from contractile forces experienced during the cardiac cycle", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Since the contractile forces can be experienced anywhere in the vascular system and are not limited to the heart wall, the claim language is considered fully met by Sogard because Sogard inherently teaches sufficient support to "maintain the patency" of a body vessel that has been "occluded, weakened, or damaged"; see page 6, lines 23-27. Since the configuration claimed encompasses any body vessel that experiences the cardiac cycle, the claim language is considered fully met. Additionally, since the composite medical device of Sogard can be delivered intraluminally, it can inherently be delivered to the "myocardial site" of a patient because "a myocardial site encompasses blood vessels surrounding or adjacent the heart muscle wall. In other words, since the Sogard device can be delivered intraluminally without any stated limitation, it flows from this fact that it can be delivered to the luminal vessels adjacent the heart muscle wall.

Regarding the arguments that Wilk does not disclose the coverings over the inner and outer surfaces. It must be noted that the claims only require the layers to cover "a portion of the surfaces" and thus amended claim 52 could still be said to be met . Additionally, claim 41 requires three features listed serially, (1) "a covering on an inner surface of the stent, (2)"an outer surface portion of the stent", and (3) "an agent for limiting thrombus formation." Since claims are given their broadest reasonable interpretation, it can be argued that the stent of Wilk has an outer surface, and that is all the claim language requires.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Th (6:30am-4pm) and alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

Brian E Pellegrino

BRIAN E. PELLEGRINO
PRIMARY EXAMINER